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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/776,844

02/11/2004

Lon J. Wilson

1789-12301

3026

23505

7590

08/20/2008

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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

08/20/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pathou@conleyrose.com

Office Action Summary	Application No. 10/776,844	Applicant(s) WILSON ET AL.	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 23 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 23 and 27-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-18,23 and 27-35 are pending in the application. Claims 19-21 were canceled and claims 33-35 newly added in the amendment filed 6/27/08. Claims 11-18 are withdrawn from consideration. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments with respect to claims 1-10,23 and 27-32 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

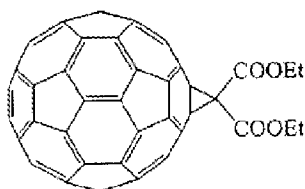
2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-10,23 and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolskar et al. (US 2003/0065206A1) in view of Yan et al. (US 5,830,539) and further in view of Kelley et al. (US 6,958,216B2).
4. Bolskar et al. (US 2003/0065206A1) discloses a derivatized fullerene comprising a malonate group (below) for water solubilization and for the incorporation of chemical handles for the attachment of other groups of biological interest (antibodies, proteins,

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peptides, ligands, drugs, etc.) (fig 1; p10, [0093]; p11, [0100]). Also, the fullerene of the disclosure may be derivatized with one or more chemical groups consisting of CR_1R_2 where R_1 and R_2 may be $P(O)(OH)_2$ (bone-targeting ligand).



5.

6. Bolskar et al. does not disclose that the group of biological interest (drug) may be antibiotics or that the targeting agents having at least one anthrax antigen bonding site, targeting agents derived from antibodies against anthrax, antibodies against anthrax spores, and combinations thereof.

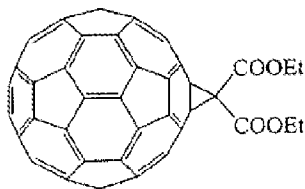
7. Yan et al. (US 5,830,539) discloses coating/functionalizing substrates, such as fullerenes with a first layer comprising a molecular tether/linker covalently bonded to the surface and a second layer comprising therapeutic agents, diagnostic agents, antibodies, etc. bonded to the first layer (abstract; column 3, lines 9-12 and 42-47; column 4, lines 12-37). The functionalized fullerenes may be converted into devices having further functional groups attached to the first layer, such as targeting ligands (i.e. antigens), antibiotics, etc. (column 6, lines 45-49; column 7, lines 60-63).

8. Kelley et al. (US 6,958,216B2) discloses carbon nanotubes chemically attached to biomolecules wherein the biomolecules interact with target species that they are designed to "sense" and detect (abstract; column 2, lines 1-6). The biomolecule, 150 nucleotide fragment of the genome of *B. anthracis* was used for detecting DNA sequences of anthrax (column 14, lines 14-61 and 65).

9. At the time of the invention it would have been obvious and predictable to one ordinarily skilled in the art to derivatize the fullerenes of Bolskar et al. with antibiotics since the disclosures of Bolskar et al. and Yan et al. are drawn to the derivatization of fullerenes with drugs, ligands, etc. It would also be obvious to one ordinarily skilled in the art to derivatize the fullerenes of the combined disclosures of Bolskar et al. and Yan et al. with targeting biomolecules that “sense” or detect anthrax as carbon nanotubes (Kelley et al.) are members of the fullerene structural family.

10. Claims 1-7,9,10,23,27-32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolskar et al. (US 2003/0065206A1) in view of Yan et al. (US 5,830,539) and further in view of Lei et al. (US 6,777,445B2).

11. Bolskar et al. (US 2003/0065206A1) discloses a derivatized fullerene comprising a malonate group (below) for water solubilization and for the incorporation of chemical handles for the attachment of other groups of biological interest (antibodies, proteins, peptides, ligands, drugs, etc.) (fig 1; p10, [0093]; p11, [0100]). Also, the fullerene of the disclosure may be derivatized with one or more chemical groups consisting of CR_1R_2 where R_1 and R_2 may be $P(O)(OH)_2$.



12.

13. Bolskar et al. does not disclose that the group of biological interest (drug) may be antibiotics or the antibodies against vascular endothelial growth factor, antibodies

against epidermal growth factor, antibodies against human tumor necrosis factor, antibodies against lung cancer polypeptides and combinations thereof.

14. Yan et al. (US 5,830,539) discloses coating/functionalizing substrates, such as fullerenes with a first layer comprising a molecular tether/linker covalently bonded to the surface and a second layer comprising therapeutic agents, diagnostic agents, antibodies, etc. bonded to the first layer (abstract; column 3, lines 9-12 and 42-47; column 4, lines 12-37). The functionalized fullerenes may be converted into devices having further functional groups attached to the first layer, such as targeting ligands (i.e. antigens), antibiotics, etc. (column 6, lines 45-49; column 7, lines 60-63).

15. Lei et al. (US 6,777,445B2) discloses a water-soluble fullerene (C₆₀) derivative to treat bacterial or viral infections, such as *E. coli*, *Staphylococcus aureus*, etc. The use includes but is not limited to the related physiological conditions inhibiting cytokine, such as tumor necrosis factor-alpha (column 2, lines 7-14; column 3, lines 8-20; column 4, lines 10-20). Administration of a pharmaceutical formulation of the fullerene to a patient may include lubricating agents, carriers or may be made into aerosols (column 6, particularly line 48). The fullerene described contains multiple PO₃H, SO₃H, and CO₂H substituents that allows for bone-targeting bound to the fullerene molecules (column 5, lines 7-8).

16. At the time of the invention it would have been obvious and predictable to one ordinarily skilled in the art to derivatize the fullerenes of Bolskar et al. with antibiotics since the disclosures of Bolskar et al. and Yan et al. are drawn to the derivatization of fullerenes with drugs, ligands, etc. It would also be obvious to one ordinarily skilled in

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the art to derivatize fullerenes of the combined disclosures of Bolskar et al. and Yan et al. with targeting moieties that target tumor necrosis factor as the derivatized fullerenes of Lei et al. are taught to treat TNF-alpha and the fullerenes of Yan et al. are taught to includes targeting ligands.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618